

**Governance Workgroup
Subgroup #2
Transcript
May 25, 2012**

Roll Call

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Good afternoon. This is Mary Jo Deering in the Office of the National Coordinator for Health IT, and this is a meeting of the HIT Policy Committee's Governance Workgroup and its subgroup number two. This is a public call and there'll be an opportunity for public comments at the end.

I'll begin by taking the role. Jonah Frohlich?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Here.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Laura Adams?

Laura Adams – Rhode Island Quality Institute –President & CEO

Here.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

John Mattison?

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Wes Rishel?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Wes, are you there?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I didn't hear my name. Yes, I'm here.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Okay. Are there any other members of the Governance Workgroup or subgroup on the call? Okay, would staff identify themselves please?

Mackenzie Robertson — Office of the National Coordinator

Mackenzie Robertson, Office of the National Coordinator.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Okay, back to you Jonah.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

All right we got the power team. So ... guys. If you could advance the slide please, we have a few questions that we have left to discuss. At our last meeting we went through questions eight, nine and ten, and today we're going to go through the remaining. We've got six questions, and I think with the three of us we should be able to knock this out in the next hour.

The six questions start with, "What successful validation models or approaches exist in other industries?" That's question 11, and then we'll go through 13, 14, 15, 16 and 17.

I don't want to go through what we did last week unless, Laura or Wes, do you have any suggested changes to the questions or our recommendations that we brought up? So maybe if we could just go for one moment to slide probably seven in this deck. Would you mind advancing it a couple please? Back one, Office of the National Coordinator's role and delegated responsibilities.

So let me just ask right here does anyone have any suggested changes to this before we move on? That this is what we validated last week? Okay, let's go to the next one please.

Make sure that we had no changes to the validation process and the voluntary nature. This process I know, Wes, we had an instant conversation with the broader group and I think we made a couple of changes here, but anything further you want to discuss?

Laura Adams – Rhode Island Quality Institute –President & CEO

I haven't had a chance to look into this. So I was hoping that we made some of the changes on the basis of that discussion with the broader group because I thought there were some very important points brought up by that group.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, I agree.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I've got no comment right now. I'm kind of looking at these fresh.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Do you want a minute looking at our responses before we get into it? Would that be helpful or do you want to proceed? I can do either way.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I guess 9a—yes, I don't feel well enough oriented to have a complete position on the second bullet either way. So I'll let it go as it stands.

Laura Adams – Rhode Island Quality Institute –President & CEO

My concern about it, Jonah, is that was it clarified that the intent, in terms of voluntary validation—from what I heard on that larger group call it was voluntary to enter into the validation process, to agree to those types of things versus a validation process where everybody just says, "Hey, I'm good," on their own. So I'm wondering about the appropriateness of our remarks in the second bullet if ... the idea of the voluntary process would not be sufficient. I wouldn't want those remarks construed, as we want this to be a mandatory inclusion of people. So I'm just a little bit worried about going forward with that language.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay. So maybe one thing we can do—in the first bullet where we said it's important to clarify the intent of the question, if we specify that our assumption about the nature of this question is that it would be

voluntary to enter into the validation process. That we feel that that would not be We are not suggesting that everybody must be able, must be required to do this in order to participate in any exchange. The clarification is entering into the validation process. Is that—?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Now I'm—where I thought I was confused before now I'm absolutely sure I'm confused. This is about NVEs or candidates for being validated, national entities. It's not about their participants right? So it's not about Sam and George's family practice. It might get some information through an HIE.

Laura Adams – Rhode Island Quality Institute –President & CEO

Right.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Okay. Now the question then is—the way I understand the options are there can be a regulation issued, there could be a regulation issued saying that in order to be an NVE you must be certified and validated. However, for many reasons, probably not the least of which is the legal authority to do it, the actual proposed regulation says there is no requirement to be certified and validated. Individual HIEs or HISPs may elect to do this because they think it'll get them more business.

Individual healthcare providers or other stakeholders may require this of HIEs if they're going to exchange information with them. Other regulations maybe issued where, for example, incentives are only available to users of certified and validated HIEs. So it could, in some sense, become pragmatically mandatory, but it is not mandatory in the sense of this regulation.

Okay, I'm comfortable with that assessment. If, in fact, the second bullet is intended to imply that the regulation should say it's mandatory, I'm not comfortable because I don't even know what that means. Mandatory to do what, to print out a shingle that has the term HIE or HISP on it to do business with the federal government? Just to say mandatory all by itself without describing the consequences isn't a very meaningful statement.

Laura Adams – Rhode Island Quality Institute –President & CEO

And, Wes, I didn't take—

John Mattison – Kaiser Permanente – Chief Medical Information Officer

I'm sorry, Laura. This is John. I just want to let you know I'm on the line. Hi, Jonah. Hi, John. Hi, Laura.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Hi, John.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

I joined about two minutes into the call. So I've heard the conversation, but I just now got the webinar going.

Laura Adams – Rhode Island Quality Institute –President & CEO

Wes, I didn't read any of this as speaking about certification or accreditation to do business. This pertains to whether or not you're going to participate in the nationwide health information network. So I saw this voluntary validation as it would be voluntary to be part of the nationwide health information network, not to operate necessarily as a HIE or be certified or accredited, but be voluntary to be part of the network.

Where that doesn't actually sing for me is when we get down here to the, "Ensuring that entities engaged in facilitating exchange continue to comply." Well if this is interpreted as just, "Hey, it's voluntary to be part of NWHIN and to accept the terms and conditions of that participation, then I don't understand why

the rest of this is here, because none of that would ensure any sort of compliance with the Office of So I still don't understand this one.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Laura, this is Mary Jo. If I could just make one clarification and it's a question of terminology. And since we all work across the standards areas we know vocabulary really matters. We actually don't try to use the language about participating in "the" nationwide health information network or joining "the" network anymore. I realize that that's the way the language reads here, but we're trying to be very careful and say you're simply validated to nationwide health information network terms and conditions. And it is different because the sense of joining something, joining an "it," joining the network, I think, is different than what we're trying to convey here.

Laura Adams – Rhode Island Quality Institute –President & CEO

I think that—I understand that and thanks for the clarification of it because I do mistakenly call it joining something when I know it's adopting instead of conditions, standards, that sort of thing. But my earlier question still stands. I don't understand it.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And I think I'm on the same page that you are, Laura. This "participation" in whatever this thing is, this agreeing to adopt a set of standards and protocols and rules, to me, what we're trying to say is it is voluntary to decide. You are not required. If you're going to be an HIO or a HIT, we are suggesting you're not going to be required to do this. It is your choice. It is voluntary if you decide you want to participate.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

This is John, if I could play that out a little bit. So let's just say that I'm a Dallas/Fort Worth HIE. We've got our own HIE locally and we've got 80% of the healthcare institutions there participating in our local HIE. So we can voluntarily go through this kind of validation process, and what do we get for that and why would we want to go through that? I'm just trying to understand the incentive model and why someone would want to do this.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right. And I think we're all struggling with that very question. In fact, we talked about it at the larger group meeting we had. I think it was earlier this week. And this is where I think we all get confused, because it's almost like joining a virtual club. Like you're hanging a shingle or you have some sort of a seal of approval.

I think what we're saying is that, I think, if you are going to be officially part of this group that agrees to adopt these CTEs, that is what you're agreeing to do, it is voluntary to do that. However, if you enter into or decide that you want to participate and adopt all of these CTEs in exchange with other entities that have decided similarly to adopt all of these CTEs, if you decide to do that, then it is required that you go through a validation process to certify or otherwise validate that you meet all of the CTE requirements.

Laura Adams – Rhode Island Quality Institute –President & CEO

That's exactly how I understand and that would be the comment that I would make. It's voluntary to get involved, whatever involvement means. It's not participating or joining or whatever, but adopting the set of protocols and so forth, but if you do make that decision to do it—I think we're saying in our second bullet point here that then the validation process isn't sort of a everybody on their own.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right, right. I almost see this as like early when in the late 90s when VeriSign was putting their seal of approval on web pages and you could post it there. To me, that's what this is. It's basically like saying, "I

have”—or it’s almost like NCQA recognizes. It’s like, “I got the seal of approval. I have my CTEs in order and I got my brand, my insignia from ...”

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

This is Wes. At a minimum I think we need to rework the wording of the second bullet in the way we’ve described, in that there is no such corporate or regulatory entity as the ‘NwHIN. It’s simply a set of standards, policies, yada yada yada. So I think we need to clarify what we mean by saying the validation process should be mandatory. At this point, we have no evidence, although we may have opinions, as to whether any of the incentives or other motivators for entering into this process exists.

And I left perhaps the most important one out, which is that the Texas HIO may want to communicate with the Louisiana HIO, and the Louisiana HIO may say, “We will only communicate with partners who have been validated.” So there are numerous potential drivers that would make it pragmatically necessary to achieve this voluntary validation.

I would argue that the sense of the question 9a is do we believe in those potential drivers? In other words, do we believe that it being voluntary will ensure that communication occurs among entities that are complying with the adopted CTEs? It’s an opinion we’re being asked.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Wes, could you just say that last line one more time?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Okay. Looking at the question—

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Wes, I only want to interrupt because I think what has become clear is that the question, as we stated it, is misleading. It’s not the validation as this group has just reconfirmed. So it’s not the validation per say. So we recognize that question is misleading.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

What is the properly led question then? To me, the question I’m asking is the only interesting question.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Well maybe, why don’t you pose your question? I should’ve have interrupted you then, but I think—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Well no, I mean if this question is not—I mean we don’t need to be discussing something that’s not on the list of questions to be answered.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Well I think it’s exactly as you’ve all stated. So I think what we’re trying to get at is would a voluntary governance mechanism be effective? I think, and again I—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

And a governance mechanism including, but not limited to the validation process.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

I don’t want to post it too finely, but I think the first part of this call you have already stated exactly what the Office of the National Coordinator intended to be the intent. How’s that?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Intending to be the intent of the question.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Yes. And once you decide you want to join or you want to get the seal of approval then you have no option but to go through the validation process.

Laura Adams – Rhode Island Quality Institute –President & CEO

Right.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes. So I'm going to take a stab. I'm not going to this right now because we have a lot to get through. I'm going to take a stab at reworking this bullet to reflect this change, because I think we're all in agreement. But, John, I want to get back to your—because you brought up a point. I want to make sure I haven't missed anything or any other thoughts you may have. But otherwise, I'm going to rework this and I'll send it out to the group, or maybe Mary Jo, you can help do that to just validate that it's worded correctly.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Okay, so I'm not going to debate your proposed change until we see it, but the question you are answering is, is that—I just don't understand the question. What does it mean to say, "I want to do it; therefore I have to do it." I mean you are either validated or you're not. If you're not validated, then you don't get into the benefits of being validated. If you are, you went through the process. So I'm just not understanding the question you're asking.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Here's another analogy perhaps, and again I think the group has said it. Driver's licenses are mandatory if you want to drive right? And you have to take a driver's test and you have to pass the test. So the question is should driver's licenses be mandatory or not, and if they're not mandatory are there enough incentives? Would it work if it were just voluntary?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

I see it a little bit differently though, Mary Jo. I see it as you can get a county driver's license or a state driver's license, but if you want to drive on the interstate maybe you need to get a national driver's license. So I think the analogy is good, but it's incomplete.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Absolutely. I quite agree with you. Thank you for that clarification.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

But I think it's an eliminating analogy in the following sense. When I go to get a driver's license I get a privilege. It's not clear to me, and I can in fact be put in jail for exercising my privilege if I don't have a driver's license. If I go for voluntary validation of my entity, my organization, it appears to me that there is no privilege that is afforded me, no regulation or law that says if I try to do something without this validation I am subject to penalty.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right. So if Louisiana and Texas agree to have ... and Louisiana and Maryland agree to have ... relationships, absent this voluntary certification, they would then have a driver's license in each of those zones but still couldn't drive through the rest of the country would be the analogy.

Laura Adams – Rhode Island Quality Institute –President & CEO

I think it was a bad analogy actually. I ...

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I'm coming to the party late and we've got a lot on our agenda. So let me look at what—Jonah, if there's any way you feel like you can restate the question that's being answered in a modified language—

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Could I try to take a shot, Wes and Jonah, at just characterizing what I see as sort of the stark alternatives? One alternative is the path that this document is on where it's sort of a voluntary thing, which allows for regional and local and statewide HIEs that do not necessarily conform to or get certified by this process.

The other stark alternative is, and that would allow any sort of paralyzed relationships to occur, the other alternative is to say if you want to be a validated node and reside in a registry of legitimate HIEs anywhere, to exchange with anybody anywhere, there's a mandatory certification process.

Am I missing something or are those the two—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

You've now created a privilege. You've now described a privilege that is available in exchange for getting validated, which is to appear in a directory. Okay, if that is somewhere implicit in this regulation that only validated entries can appear in directories, then I understand the question a lot better.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Well I was proposing that that is a very different model from what—I'm saying that what's before us does not reflect that, but I'm saying—we're nibbling on the edges of that alternative that I described.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Well I would say that if the question were absent a regulatory privilege, or the absence of a regulatory penalty that enables one to do the activity of an HIE, if the assumption is there is none, will the voluntary program be effective? I'd be willing to consider answering yes, because I believe that the various considerations that we have described would cause trading partners to limit their activities to entities that have been validated, simply because it avoids so much due diligence one partner at a time. So in that, with the right assumptions, my entire answer to 9a would be yes.

Laura Adams – Rhode Island Quality Institute –President & CEO

I have a little bit of trouble understanding that this effective here is effective for getting people to participate or effective in making sure that those that are engaged comply with the CTEs, and I'm hearing it as the later. I didn't hear this as would voluntary validation—

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Well I'm hearing it as the later too. In other words—well I guess there's another question about is validation a one time activity or is there some requirement to revalidate as often as you get a driver's license or something?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right. And I think we're really only focusing on—I don't want us to go too far down the rabbit hole about an ongoing process and I also read this as being voluntary validation process for effective compliance with adopted CTEs, the second component. So I read it the same way.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Okay. I think if you simply amend our response to state what you think we're agreeing to then I think we ought to be fine.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

I will do that, in order for us to get on to the next question.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Yes, good idea.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

And Jonah, if you don't mind I'll just add one last closing comment. I, like Wes, think that it's okay to go with this voluntary model under the premise that Mary Jo started off with that there is no "it." So as long as we're operating under the assumption base that we're talking about standards and processes and so forth and not an "it" then voluntary makes perfect sense. Once it becomes a more rigorously defined "it" then mandatory would become more reasonable.

I'm just trying to characterize the stark difference between with and without "it" and with and without mandatory. And I'm okay going with a voluntary path, but we just need to be eyes wide open about what the implications are.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay. Thank you. All right, so I think 9b, I don't think there were any other contentious areas that came up that were kind of left hanging, unless you all feel that there were some issues with these other responses. But in terms of—if you move forward please a couple of slides to question ten, the validation method—we discussed it then I don't think there is any problem with our response here or our recommendation.

So I'm going to move on to ten and we'll be able to present these in total once we get all these completed. But if we could move to number 11 please, the comparative model, the validation process, this may be very quick.

I'm not aware, I just don't know other industries well enough to raise the issue of are there other validation models in other industries that could be used as a model for our purposes in this context. John, Laura, Wes, do you have any thoughts about other industry kind of validation processes that we may want to use as a model here?

Jan Root – Utah Health Information Network

Jonah, this is Jan Root. Sorry, I joined a while ago and I've just been lurking.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Hi, Jan.

Jan Root – Utah Health Information Network

Are you talking about outside of health care or including other models inside of health care?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Other industries, non-healthcare.

Jan Root – Utah Health Information Network

Non-health care. If you look at banking, banking has similar, NACHA does things like this.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right, but NACHA has transaction standards that are voluntary. Well do we know enough about them? Do we know if NACHA—is it voluntary to comply with those standards or if you're going to be part of the network, it's not voluntary right?

Jan Root – Utah Health Information Network

I don't know much about NACHA. I'm just learning about them, but I think they're pretty rigorous.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And that is an "it." That is a physical network.

Jan Root – Utah Health Information Network

It is a physical network, yes.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

This is John. I'm wondering if we might want to explore some of the things that ISO has done, because I think they cover the whole range of standards across multiple industries? There might be some very useful comparisons that they could share, tradeoffs pros and cons based upon their experience with some of their different standards.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I would agree that they have numerous models for the structure that is described in this RFI, which is to say that there is a master organization that authenticates authenticators or authorizes authorizers, and the body of evaluation of compliance to the standard is by this second level of authorizers. I don't actually know, and that doesn't mean it doesn't exist, but I don't know of one where the thing that is being evaluated has anything to do with interconnection. It typically has to do with quality standards or other kinds of, if you will, softer sets of criteria where you can't say the data went accurately or it didn't go accurately at the end or got shared in an unauthorized way or not.

There's the PCI, the Payment Card Industry Data Security Standard, which I'm looking at the Wikipedia description of it right now. It is—it has several similarities in that it describes conditions for trusted exchange of payment transactions and information about the objects of payment transitions, the consumers and the banks. It doesn't describe a single "it" in the sense that there are several networks of payment card transactions, American Express, MasterCard, Visa and a few odd other ones, all of which use the PCI Data Security Standard and a governance mechanism for deciding how to evaluate in order to secure compliance. And I believe that it's mandatory. I really don't know this for sure, but I believe that if you are T.J.Maxx and you haven't been audited according to PCI, you can't do credit card transactions.

Laura Adams – Rhode Island Quality Institute –President & CEO

This might not be relevant since it is a network. I know that Surescripts sort of validate the credits, maybe that just has to do with purer standards, I'm not sure, and given that it's a closed network I don't know if there's anything to learn from that model.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

I think kind of like NACHA it's a condition too. You have to be Surescripts certified in order to be allowed to use the Surescripts' network, which is a ... thing right?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

In this case, a vendor has to be Surescripts certified and the vendor's client has to be certified to the extent of being a proper kind of organization, one that can write prescriptions. And Surescripts delegates

that second level of authorization to vendors after having qualified the vendors. I think it's a good example, but it's in our industry.

Laura Adams – Rhode Island Quality Institute –President & CEO

Right, that's right.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I think that the CLIA Lab certification is another example that's in our industry. The good part being that they actually insist on going end to end. That is looking at the data coming off an instrument and looking at the data displayed to the physician on EHR and ascertaining that it's the same information displayed in the way that's understood and safe according to their standards for safety.

However, somebody just told me last night—I actually don't believe it. I'm having a hard time just believing this guy—that their model for HIE doesn't go end-to-end. It only goes from the lab to the HIE, and that's news to me.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So Surescripts and CLIA accreditation are potentially within our industry example. There's another, and I kind of motioned this before, but you know the TRUSTe seal of approval that exists, and this is just one of the many kinds of seals of approvals that exist on websites.

My understanding is that, and I'm just using TRUSTe as an example, but they're fairly well known, is that as a website if you go through TRUSTe's own certification process then TRUSTe will review the website's privacy policies and make sure that it adheres to it. You are then able to put that insignia on your website that is supposed to provide some level of assurance that you are in compliance with the set of rules that other people feel are adequate to protect privacy.

Is that another one we want to raise?

Laura Adams – Rhode Island Quality Institute –President & CEO

I think that's a pretty good one because it does have that aspect of privacy, which is what most people—and I realize it's not iron clad, but I do think that at least has some relevance to what we're talking about here.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And they've got privacy seals and security seals and reputation reliability seals. So they actually have different categories. So maybe we can bring these up as some potential models that the Office of the National Coordinator should be looking at.

Laura Adams – Rhode Island Quality Institute –President & CEO

There's also the eMac model, and again it doesn't control a network but it is an amazingly thorough top-to-bottom scrub of privacy and security and how you treat your customers and basically overall performance, like what's been your system availability over the last year, stuff like that. I mean we're just completing our 2012 one and one accreditation, just the basic part of it when we finished ..., is 155 pages long. It's very, very thorough.

One thing to think about, it is very useful to look at examples from other industries, but health care is very unique and I think whatever we come up with, one, you don't want to reinvent the wheel, whatever you do, and two, its not always applicable to pull concepts from other industries.

For example, on the CTE list, one of them is talking about allowing patients to correct information. HIPAA avoided the word correct, correcting clinical data with, I think, admirable restraint. And they use amend. You know you can correct financial information, but clinical information, the correctness of it can be in the eye of the beholder, so just a caution.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Unfortunately I prefer append to amend because amend can include corrections.

Laura Adams – Rhode Island Quality Institute –President & CEO

Yes, and that would be better even.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

The HIPAA language only goes so far as to request an amendment and then has some obligations on the source of the data to deal with the request. I agree that that's the appropriate thing for health care.

On the other hand, I think that on the average, health care spends too little time looking at what's going on in other industries rather than slavishly adopting what's going on in other industries. If we had started DICOM on the premise that we could use standard cable rather than we had to design our own cable in order to exchange images, DICOM would've moved a lot faster.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So if I can propose here that it sounds like we have a few examples that we may want to raise and that we would recommend.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

I have another one to raise, which is ACORD, ACORD. It is a set of data standards for exchanging information on non-healthcare policies. They have a certification. The organization that writes the standards itself does certification. The first requirement that you have in order to get certified is to join ACORD. They also certify experts. That is they certify people on expertise in ACORD, as well as certifying entities on interoperability.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Just so we know here, what do they certify them to do? What does that enable an entity—?

John Mattison – Kaiser Permanente – Chief Medical Information Officer

To exchange information about property and casualty applications, life and annuity, property and casualty, T&C, surety and reinsurance and large commercial insurance applications and claims, I think.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay. So does the worker feel comfortable with making a recommendation that the Office of the National Coordinator should consider a few models outside of health care for a validation process including the PCI, the Payment Card Industry Security Standard, the TRUSTe model for certifying compliance with privacy policies, the ACORD standards for certifying people or entities around things like exchanging information for property and casualty insurance etc., and then a few models within healthcare that may also be considered; Surescripts, CLIA, and eMac.

Laura Adams – Rhode Island Quality Institute –President & CEO

I like it.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Awesome. All right, let's keep going. We're now getting to the NwHIN validation entity eligibility criteria. If you could please advance the slide one, you can see that this is what you have in terms of the eligibility criteria that is listed in the RFI. So these are the eligibility criteria and the question on the next page—do you all need a minute to read these?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Yes.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, I'll give you a moment then.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Okay.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Excellent. Everybody else, you're good to move?

Laura Adams – Rhode Island Quality Institute –President & CEO

Yes. Wait. What is at least one year of experience? In what? In what?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

That's the one I focused on too.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So should we add a clarifying question? And the question is one year of experience doing what?

Laura Adams – Rhode Island Quality Institute –President & CEO

Yes. I mean does it just mean they have to be in business for a year? I mean you could've—

John Mattison – Kaiser Permanente – Chief Medical Information Officer

...the only way you can become an MVE is to have been an MVE for a year.

Laura Adams – Rhode Island Quality Institute –President & CEO

That sounds wonderfully Let's do that.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

That would certainly take us right to voluntary.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay. So I will ask that the worker wants this to be clarified to be one year to do what? One year of experiencing doing what?

Laura Adams – Rhode Island Quality Institute –President & CEO

Can I ask one more question? Under the, "Have not had civil monetary ... " somewhere sort of towards the bottom of the list. So if you get a HIPAA violation does that mean you're kicked out of this for two years?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

It means you're not eligible right. Do you mean are you not eligible or do you actually get kicked out?

Laura Adams – Rhode Island Quality Institute –President & CEO

Do you actually get kicked out? Assuming you did it. You got in. You're all good. HR's had this huge breach—

John Mattison – Kaiser Permanente – Chief Medical Information Officer

I'm actually glad you brought that up because we discussed that issue in the NwHIN extensively, and quite honestly when you have 165,000 employees like we do you have rogue people who, despite their annual compliance training, incur HIPAA violations. Does that mean all of Kaiser Permanente is taken out of business because one of our employees did something stupid? We'll never qualify under that with 165,000 people and the rogue players that we fire on a routine basis.

Laura Adams – Rhode Island Quality Institute –President & CEO

Yes. So I think that needs a lot of clarification.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I actually think that that—my recommendation would be that should be struck.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

The way we kind of addressed it and what I proposed was that there be some—either strike it all together or have some threshold of egregious behavior. But a HIPAA violation, it means somebody did something wrong, somewhere, someday in your organization.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

This is Mary Jo. I'm not a lawyer, but does the word enjoined make a difference? In other words there's a difference between the fact of someone having done something and is there a legal aspect here that you have been formally enjoined and that that's what this is getting at?

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Let me test that a bit because I've been to two conferences where a security expert on a stage has said, "I can't believe that the State of California imposed a \$750,000 fine in the Octomom case when everything done was per protocol." So when an agency wants to make an example, to make a point, even an injunction can be over represented as a valid metric for an egregious act. So this is a very treacherous statement.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

In any event it it's an "or." It's or enjoined it's not and enjoined.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So I'm going to suggest that we note two issues. One is the one-year experience doing what? We need that clarified. We would recommend it clarified. Two, eligibility criteria regarding HIPAA violation needs to be carefully reconsidered. We actually weren't asked to validate the criteria, but I think it's really important that we note our concerns about those two.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

And, Jonah, let me just mention one other point. So let's just say that Mayo Clinic is enjoined and they're taking off. So what that means is everybody who's seen at Mayo Clinic or everybody who has a record at Mayo Clinic may not benefit from the quality of care delivered to the exchange of their single record after such a moment of injunction. And is it really the institution or is it the individual—? So there's a whole raft of issues, but I would stay strike it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I would say we've got an issue that Jonah has raised about what questions did they ask us, but I think we're all in agreement that the criterion, as listed here, is one, rather vague, b.) Likely to select good players and has deleterious consequences for patients. If there's going to be any such condition, it needs to be much more carefully wrought.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes, okay. Then having said that, which I think is a good summary statement, on the next page the question that we are being asked specifically, there are actually a few questions. I don't think the—let's just address the first one. Should there be an eligibility criterion that required an entity to have a valid purpose for exchanging health information?

So if we think of the flip side, is there any reason why anybody with no explicit purpose should be required, should be allowed to exchange health information?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Well I would propose that—I mean we keep—most of our discussions have been framed to an old model of state enabled HIOs that are nonprofits running for the public good. But we have to be addressing a much broader scope of possibilities, including commercial for-profit companies and including for-profit or not-for-profit healthcare delivery organizations that choose to engage, choose to operate as an NVE. So at least one valid reason should be, "I want to make money doing this." What's left? If we're trying to weed out bad actors, we can't expect bad actors to be upfront about what their purpose is.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

There are honest bad actors out there, Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Oh really? Yes, I think I bought a car from one.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So I guess what we're saying—so if we want to be responsive to this question, it's an odd question. It's a strange way of framing it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I'm going to assume that they had some internal rhubarb about this that was difficult to resolve and it's worth taking what we've said, which is that it's hard to imagine a definition that's effective and put it back just to help some unknown person deal with some other unknown person internally.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

And I think if this makes sense that it is more important to have a clear set of eligibility criteria from the discussion we just had than it is to define a valid purpose—

Jan Root – Utah Health Information Network

So you're saying we shouldn't answer this question of whether or not there should be a criterion that requires a valid purpose ... to what you said before?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Yes.

Jan Root – Utah Health Information Network

Maybe you just have to state your purpose. I mean I think PPO, right, those are all okay, this is Jan again, but maybe, I don't know—but the gentleman who said that the bad actors are not going to be honest about it that certainly is true. So I guess the question is what's the purpose of this meeting?

John Mattison – Kaiser Permanente – Chief Medical Information Officer

It's what's the purpose of whom? It's what the purpose of the NVE right? Not the purpose of the end exchange. I would assume that most NVEs would say their purpose is to enable all valid and legal exchanges of healthcare information.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

But maybe this is back to Jan, your suggestion that we recommend that NVE should simply state the purpose of engaging an exchange and leave it at that.

Jan Root – Utah Health Information Network

Again, I think that gets to no bad actor's going to say what their purpose is. So is this designed to limit the use of information for treatment only?

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right.

Jan Root – Utah Health Information Network

I actually don't think we want to go there in the sense that if it limits some other legitimate uses of the information, but I think that's the essence of this. That this should be required. This type of exchange limited to the purposes of treatment only.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Right. And I think what we're saying here, I think what we are coming to the conclusion here about recommendation, is that we should not necessarily predetermine or pre-constrain how entities decide to exchange and for what purpose. There might be a very valid reason for secondary use, for research, for investigation, for legal investigation that all complies with federal and state rules, but if we start to put a list out we may not have thought of something. And the regulation, if it starts to draw a list, may not have appropriately or adequately considered all valid uses of exchange.

Jan Root – Utah Health Information Network

I like the idea that the purposes here just have to comply with federal and state laws.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I like Jan's suggestion because it goes more to the transparency than regulating the use. It's not the question to ask that they didn't say should there be a statement of intended use? They asked us should there be an eligibility criterion that requires a valid purpose? I think my short answer to 13a would be no. A longer answer would be there might be value in requiring public statement of the purposes supported by an NVE.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

This is Mary Jo. And just for the record once a public statement is made of purpose then FTC Oversight kicks in. So having them somewhere publicly say what they do then if they don't do that or if they do things that are countered to what they've said they do, then the FTC has jurisdiction.

Laura Adams – Rhode Island Quality Institute –President & CEO

Terrific.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Do we want that?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Yes.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

I would say yes.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

So FTC jurisdiction, okay, I'm totally fine with this. Our basic answer is no; there should not be an eligibility criterion that specifies the purpose. However, we would recommend that any NVE publicly state their purpose for engaging in exchange which would invoke FTC jurisdiction and that NVEs per previous requirements meet federal and state rules around privacy, security and exchange.

Jan Root – Utah Health Information Network

This is Jan. There's a problem you're going to run into eventually, you don't need to worry about it right now, and that is for non-covered entities. For example, we're working with Property and Casualty. They are not a covered entity. Anyway, that's not an issue right now. I just raise it as something to worry about later, 3:00 in the morning, whatever.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

The way I read the regulation or the RFI the intent is to require all NVEs to follow the HIPAA requirements whether or not they're covered entities.

Jan Root – Utah Health Information Network

I understand that. I'm just saying, if, in the future, we wanted to open it to non-covered entities such as Property and Casualty, they will have a big problem with that. They would argue, and I'm not sure I agree with them, but they would argue that they have plenty of privacy and security through ... and all the finance—they're considered a financial institution. Anyway, I just want to say that's an issue that we're chewing on right now. I'm not trying to change anything.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

In the interest of time check, it is almost time to end the call. I didn't know if you wanted to take a fast stab at question at 14 or wanted to—

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Could I just make one closing comment on 13? That is there are two things we're trying to protect against. The first is creating an exhaustive list of what would be eligible uses because we can't anticipate them all. The second is to have a way of detecting and addressing things like medical identity theft for purposes of fraudulent billing. So I think the two principles we're trying to address in 13 should help guide how we create the solution.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay. So I think what we're coming around to is should there be an eligibility criterion? The answer is no. However, there may be value in requiring a public statement of their purpose, which would invoke

FTC jurisdiction for all NVEs. It's hard to imagine a definition that would anticipate all appropriate uses. This is part of substantiating our answer. And per the RFI, the protections need to extend—we agree that these protections need to extend to protect indent theft, etc., and I think that's it.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Sounds good.

Laura Adams – Rhode Island Quality Institute –President & CEO

Sounds very good.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

13b is not applicable because we are not stating that. We turn that down. It is 11:30 and we're not done, sadly. Oh boy. So I think we're going to have to figure out another time to finish this off.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

We do have another meeting.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

We do? Excellent, then we'll do it then.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

When is that again?

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

It is on the 29th, 4:00-5:00 p.m.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Eastern?

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Eastern Time, May 29th, 4:00-5:00 p.m.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Okay, thank you.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Okay, do we need to open it up for—?

Public Comment

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

We certainly do. Operator, would you go ahead and open for public comment please?

Operator

If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

We have no comments at this time.

Jonah Frohlich – Manatt, Phelps & Phillips, LLP

Hot dog. Thanks, everybody. I'm sorry I couldn't get us all through the entire questions today, but I appreciate your thoughtful responses here. Thank you, Mary Jo.

Mary Jo Deering – Office of the National Coordinator – Senior Policy Advisor

Thank you, everybody, have a good holiday weekend.